REMARKS

I. INTRODUCTION

First claims 149-151 and second claim 149 have been cancelled above, without prejudice. Claims 68, 81, 89, 101, 103, 113, 125 , 131 and 147 have been amended above merely to clarify the subject matter recited therein, and remove minor informalities therefrom, but not for any reason relating to patentability thereof. New claims 161 and 162 have been added above, and correspond to the previously-pending and now-cancelled first claims 150 and 151. Accordingly, claims 68-148 and 150-162 are now under consideration in the above-referenced application. Provided above, please find a claim listing indicating the cancellation of first claims 149-151 and second claim 149, the amendments of claims 68, 81, 89, 101, 103, 113, 125 , 131 and 147, the addition of new claims 161 and 162, and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. OBJECTIONS TO CLAIMS SHOULD BE WITHDRAWN

Claims 101, 103 and 155 stand objected to due to certain minor informalities. As the Examiner shall ascertain, claims 101 and 103 have been amended, and first and second claim 149 have been cancelled above to address such minor informalities. Accordingly, the objection to claims 101, 103 and 155 is now moot, and should therefore be withdrawn.

In addition, the Examiner objected to the claims not being in a consecutive order, as claims 149-151 appear twice in the claims. As the Examiner shall ascertain, first

set of claims 149-151 and second claim 149 have been cancelled above, without prejudice. Further, new claims 161 and 162 have been added above, and correspond to the previously-pending and now-cancelled first claims 150 and 151. Accordingly, claims 1-148 and 150-162 are now pending in the present application (in a consecutive order), and thus the objection to the claims should be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 103(a) SHOULD BE WITHDRAWN

Claims 68-75, 81, 82, 84-87, 89-95, 101, 102, 104-107, 109-116, 118-128, 130, 137-140, 142-145 and 147-157 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,318,024 issued to Kittrell et al. (the "Kittrell Patent"). Claims 83, 88, 103, 108, 117, 129, 131-136, 141, 146 and 158-160 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 3,941,121 issued to Olinger et al. (the "Olinger Patent"). Claims 76-78 and 96-98 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of International Publication No. WO 99/44089 by Webb et al. (the "Webb Publication"). Claims 79, 80, 99 and 100 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 5,275,594 issued to Baker et al. (the "Baker Patent"). Applicants respectfully assert that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, fails to teach, suggest or disclose the subject matter recited in amended independent claims 68, 89, 113, 125 and 131, and the claims which depend therefrom, for at least the following reasons.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently

described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Machinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the "TSM test"). *See In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, *see KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the

Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; *see In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. *See In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be

considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Kittrell Patent describes a laser endoscope for generating a spectrally resolved spatial image of tissue. Fiber optics positioned within an optically shielded endoscope are used to deliver laser radiation to tissue to be imaged. Radiation returning through the fiber optics from the tissue is spectrally resolved and used to generate an image of tissue that can assist in diagnosis and treatment. (See Kittrell Patent, Abstract).

A generalized spectral system is shown in Figs. 21 and 22 of the Kittrell Patent. As illustrated in Fig. 21, an excitation light 95 is sent from a laser or conventional light source into a selected optical fiber 20. This light passes through a beam splitter 52 or a mirror with a hole 50 (as shown in Fig. 22), and focused onto the input end 40 by a lens 41. The light exits the distal end of the optical fiber 20, passes through the optical shield 12, and impinges on the tissue 34 (of Fig. 4). The fluorescence and scattered light is returned via the same or a different optical fiber 20 to the proximal end 40 of the optical fiber 20. This return light 54 is separated by the beam splitter 52 or by the mirror 50 with hole 51 (see Fig. 22), and enters a spectrum analyzer 60. A diffraction grating 68 of the spectral detector 65 can disperse the return light from a target. The dispersed light is projected onto a multichannel detector 70 which has many detectors. (See *id.*, col. 19, lns. 20-47). Fig. 13B of the Kittrell Patent illustrates the use of a prism, but without any lens.

The Olinger Patent relates to a needle endoscope includes a hollow needle of about 18-gauge, a lens system within the needle, an image transmitting bundle of flexible fiber-optic rods within the needle, a plurality of illumination transmitting fiber-optic rods

within the needle, an operative channel within the needle, and apparatus to shift the image transmitting bundle with respect to the lens system and needle to provide focus adjustment for focusing the endoscope on objects at various distances from the end of the needle. (See Olinger Patent, Abstract).

The Webb Publication relates to a scanning confocal microscopy system, especially useful for endoscopy with a flexible probe which is connected to the end of an optical fiber (9). The probe has a grating (12) and a lens (14) which delivers a beam of multi-spectral light having spectral components which extend in one dimension across a region of an object and which is moved to scan in another dimension. The reflected confocal spectrum is measured to provide an image of the region. (See Webb Publication, Abstract).

The Baker Patent relates to angioplasty system and method for identification and laser ablation of atherosclerotic plaque at a target site in a blood vessel. Such system and method employ fluorescence analysis for identification of noncalcified plaque and calcium photoemission analysis for identification of calcified plaque. Calcified plaque is identified by time domain analysis of calcium photoemission. A high energy pulsed ultraviolet laser can be used for stimulation of fluorescence and for stimulation of calcium photoemission. The system is capable of distinguishing between calcium photoemission and a defective condition of optical fibers that are used to deliver laser energy to the target site. In an another embodiment of the angioplasty system, calcium photoemission is identified during a nonablative initial portion of the laser ablation pulse. When calcium photoemission is not identified, the laser ablation pulse is terminated during the initial nonablative portion thereof. (See Baker Patent, Abstract).

Applicants' invention, as recited in amended independent claim 68, relates to an apparatus for obtaining information associated with a structure which comprises, *inter alia*:

> **an image-forming lens arrangement which is configured to provide there through electro-magnetic radiation**; and
>
> **a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation** and **forward a dispersed radiation thereof to at least one section of the structure regarding which the information is being obtained**

Applicants' invention, as recited in amended independent claim 89, relates to an apparatus for obtaining diagnostic information associated with a structure and modifying at least one property of at least one portion of the structure which comprises, *inter alia*:

> **an image-forming lens arrangement** and a plurality of fibers **configured to provide there through the electro-magnetic radiation, at least one first fiber of the fibers being configured to provide a first electro-magnetic radiation to the at least one portion of the structure regarding which the information is being obtained** so as to obtain the information, and at least one second fiber of the fibers configured to provide a second electro-magnetic radiation to the at least one portion so as to modify the at least one property; and
>
> **a dispersive arrangement configured to receive the first and second electromagnetic radiations**.

Applicants' invention, as recited in amended independent claim 113, relates to an apparatus for obtaining information associated with a structure which comprises, *inter alia*:

> **an image-forming lens arrangement configured to provide a plurality of electro-magnetic radiations**, and **a dispersive arrangement configured to receive the electro-magnetic radiations** and **forward a dispersed radiation of each of the electro-magnetic radiations to at least one portion of the structure**

> **regarding which the information is being obtained** and at least partially overlap the at least one portion ... .

Applicants' invention, as recited in amended independent claim 125, relates to an apparatus for obtaining information for a structure which comprises, *inter alia*:

> **an image-forming lens arrangement configured to provide an electro-magnetic radiation**, and **a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation and forward a dispersed radiation thereof to a particular location on at least one portion of the structure regarding which the information is being obtained** ... .

Applicants' invention, as recited in amended independent claim 131, relates to an apparatus for obtaining information associated with a structure which comprises, *inter alia*:

> **an image-forming lens arrangement which is configured to provide there through electro-magnetic radiation**; and
>
> **a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation** and **forward a dispersed radiation thereof to at least one portion of the structure regarding which the information is being obtained** ... .

Thus, each of amended independent claims 68, 89, 113, 125 and 131 recites an "image-forming lens arrangement" and a "dispersive arrangement" and that the radiation is forwarded to at least one portion of a "structure regarding which the information is being obtained."

In the latest Office Action, the Examiner contends that the Kittrell Patent, at col. 7, lns. 57-63 thereof, describes that the "optical shield 12 is a transparent enclosure made of fused silica, glass or sapphire or other optically-transparent material ...", and equates such optical shield 12 of the Kittrell Patent to the lens arrangement as recited in

previously-pending independent claims 68, 89, 113, 125 and 131. (See Office Action dated November 12, 2009, p. 2, lns. 13-15).

Independent claims 68, 89, 113, 125 and 131 have been amended to recite that the lens arrangement is an "**image-forming lens arrangement**". As an initial matter, Applicants respectfully assert that the Examiner's allegation regarding the alleged correspondence the transparent shield/enclosure 12 of the Kittrell Patent to the now-recited "image-forming lens arrangement" of the amended independent claims is inapplicable. This is at least because the transparent shield/enclosure 12 of the Kittrell Patent does not change the characteristics of the radiation being transmitted therethrough. In addition, the amendment of the independent claims to recite such "image-forming lens arrangement" certainly distinguishes such recited subject matter of amended independent claims 68, 89, 113, 125 and 131 from the disclosure of the Kittrell Patent. Indeed, the transparent shield/enclosure 12 of the Kittrell Patent does not and cannot be equated to the image-forming lens arrangement of the amended independent claims at least because the transparent enclosure of the Kittrell Patent does not provide or form any image. For example, the formula for forming the image is as follows:

$$1/f = (n-1)(1/R_1 - 1/R_2)$$

where f is the focal length, n is the refractive index of the lens material, and R1 and R2 are the radii of curvature of the front and back sides of the lens.

As shown in Figs. 13A-13F of the Kittrell Patent, the transparent shield/enclosure 12 appears to have an equal distance between the inner surface and the outer surface along the section thereof through which the radiation is exhibited. Thus, R1 and R2 of the shield 12 of the Kittrell Patent are the same, and the formula above yields

that the element f (focal length) goes to infinity. Therefore, no image can be formed thereby.

In addition, the lens 41 of the Kittrell Patent which forwards the radiation from a laser to the fibers 20 also do not provide or form any images, and thus cannot be equated to the "**image-forming lens arrangement**", as recited in amended independent claims 68, 89, 113, 125 and 131.

The Olinger Patent, the Webb Publication and/or the Baker Patent do not cure such deficiencies of the Kittrell Patent, and the Examiner does not contend that they do.

Accordingly, Applicants respectfully submit that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, does not render obvious the subject matter recited in amended independent claim 68, 89, 113, 125 and 131. The claims which depend from such independent claims are also not taught, suggested or disclosed by the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent for at least the same reasons.

Further, regarding claims 83 and 103, these claims depend from independent claims 68 and 89, respectively, and further now include the recitation of **a fluid displacement arrangement acts on the dispersive arrangement**. The Examiner appears to be attempting to combine the Olinger Patent with the Kittrell Patent to allegedly teach or suggest such subject matter, and contends that the Olinger Patent uses a saline solution to clear the area for examination to allow for better viewing. (See Office Action dated November 12, 2009, p. 2, 17-19). However, even if, *arguendo*, the Olinger Patent

describes a use of a fluid displacement arrangement, the Olinger Patent fails to cure the deficiencies of the Kittrell Patent to teach or suggest that any such fluid displacement arrangement ***acts on*** *the dispersive arrangement*. No such *action* is even mentioned, much less taught or suggested in the Olinger Patent. Merely because the saline solution is used to clear the area for better viewing in **now way provides any action on the dispersive arrangement**, as recited in claims 83 and 103. Indeed, while the saline solution of the Olinger Patent acts on the surrounding area of the probe, it in no way acts on the endoscope device, much less on the dispersive arrangement as recited in claims 83 and 103.

With respect to claims 142-146, these claims depend from independent claims 68, 89, 113, 125 and 131, respectively, and further now include the amended recitation that **the dispersive arrangement is structured to provide at least 100 spectrally-resolvable points without a controlled mechanical motion**. Indeed, as previously indicated, none of the configurations of Kittrell would be able to provide at least 100 spectrally-resolved points on the sample (without a controlled mechanical motion), at least because no lens is disclosed to be in combination with the dispersive arrangement (providing disperse radiation to the sample). The Kittrell Patent indicates that every point on the image is associated with the spectrum of light returned from the tissue.

In the latest Office Action, the Examiner contends that the lens establishes the number of spectrally-resolved points, and that it would be obvious to provide such points as recited in these claims. (See Office Action dated November 12, 2010., p. 3, lns. 7-10). However, according to the recitations of claims 142-146, it is the dispersive

arrangement (*and not the lens* as alleged by the Examiner) that is structured and/or establishes the number of spectrally-resolved points.

Indeed, the Examiner believes that the number of the resolvable points can be anything between 0 to infinity (i.e., using the disclosure of the Kittrell Patent). The Kittrell Patent describes the number of such points to be zero, but it clearly does not disclose that such number can be more than at least 100 spectrally-resolved points on the sample. This is because the number of the resolvable points depends on the imaging characteristics of the lens and groove density of the grading. Again, in the Kittrell Patent, there is no description of illustration of the lens-grading pair, much less the characteristics of such lens-grading pair to make the ability to provide at least 100 spectrally-resolved points on the sample possible.

Regarding amended claim 147, these claims depend from independent claims 74 and independent claim 68, and also recites that "**the optical fiber has an end portion that is provided at a position of an image plane of the at least one portion which is established by the lens**." In the latest Office Action, the Examiner now agrees that such subject matter is not disclosed in the Kittrell Patent, but contends that the "the end of the optical fiber, and therefore, the endoscope would be at least near the image plane which is established by the lens." (See Office Action dated November 12, 2009, p. 2, lns. 13-16.) The Examiner also contends that the lens "would be the optical shield). However, as indicated herein above, claim 147 has been amended above to recite that the end portion of the optical fiber is provided <u>at a position of an image plane of at least one portion established by the plane</u>. Clearly, no such subject matter is taught, suggested or disclosed by the Kittrell Patent.

Thus, for at least these reasons, withdrawal of the rejections of these claims under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested.

IV. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims 68-148 and 150-162 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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